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EXAMINER

THORNTON, L.

ART UNIT

3763

PAPER NUMBER

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Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/051,290

Applicant(s)

Moreau Defarges et al.

Examiner

LoAn Thanh

Group Art Unit

3763

☒ Responsive to communication(s) filed on Jun 18, 1999

☒ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 2-13 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☒ Claim(s) 8-11 is/are allowed.

☒ Claim(s) 2-7, 12, and 13 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

Art Unit: 3763

DETAILED ACTION

Response to Amendment

1. The drawing objections have been withdrawn in view of the amendments and the remarks with the exception paragraph 3 of the Office action and the proposed drawing amendment (pg. 2). The drawing is still objected to since reference numeral 3 and 55 are designated as "cap".
2. The specification is still objected to under 35 USC 112, first paragraph because it has not been addressed in an adequate manner to make clear to the Examiner.

Drawings

3. Applicant is required to submit a proposed drawing correction in reply to this Office action. However, formal correction of the noted defect can be deferred until the application is allowed by the examiner.
4. The drawing is objected to because the cap has been designated as "3" and "55".
Correction is required.

Specification

5. The disclosure is objected to because of the following informalities:

The cap has been designated as "3" and "55".

Art Unit: 3763

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following is a quotation of 37 CFR 1.71(a)-(c):

(a) The specification must include a written description of the invention or discovery and of the manner and process of making and using the same, and is required to be in such full, clear, concise, and exact terms as to enable any person skilled in the art or science to which the invention or discovery appertains, or with which it is most nearly connected, to make and use the same.

(b) The specification must set forth the precise invention for which a patent is solicited, in such manner as to distinguish it from other inventions and from what is old. It must describe completely a specific embodiment of the process, machine, manufacture, composition of matter or improvement invented, and must explain the mode of operation or principle whenever applicable. The best mode contemplated by the inventor of carrying out his invention must be set forth.

(c) In the case of an improvement, the specification must particularly point out the part or parts of the process, machine, manufacture, or composition of matter to which the improvement relates, and the description should be confined to the specific improvement and to such parts as necessarily cooperate with it or as may be necessary to a complete understanding or description of it.

The specification is objected to under 37 CFR 1.71 because it fails to adequately teach how to make and/or use the invention, i.e, failing to provide an enabling disclosure. It is unclear whether Applicant has the reverse intentions for the safety device on page 5 lines 7-14. Is the locked safety device when the percussion device cannot be armed and when it is unlocked the percussion device is in the trigger position? It is unclear how the safety device can function safely if it is unlocked that it cannot arm the percussion and when it is locked it can arm the percussion device. It is further unclear what elements comprises the percussion device. Is it only the striker and the rod?

Art Unit: 3763

Claim Rejections - 35 USC § 112

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 3-9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 3 is vague and indefinite because it is unclear what "if appropriate" is intended. It is ambiguous whether Applicant is claiming the tinted plastic material or not.

9. Claim 4 is vague and indefinite because it is unclear whether the rod is the percussion member or part of the percussion member. Further, since the diameter of the rod and the percussion member is not positively claimed it lacks proper antecedent basis in line 5. It is further indefinite because it is unclear if Applicant is claiming the combination of the "the cartridge" and "the injection device" or the subcombination of the "cartridge" alone. This lack of definiteness arises from the clear indication in the preamble that Applicant intends to claim only the above subcombination, but Applicant goes on in the claim(s) to positively recite the combination. The claim is considered as having been drawn to the combination. If Applicant indicated by amendment that the combination claim is the intention, the language in the preamble should be made consistent with the language in the body. If indicated that the intent is to claim the subcombination only, the body of the claim must be amended to remove any positive recitation of the combination. (i.e. the rod and the percussion member).

Art Unit: 3763

Claim 5 is vague and indefinite because it is unclear what "at one of its ends" is intended and what structure this encompasses. It is further unclear if there are more than one end then which end is Applicant referring to. It further lacks antecedent basis since there is no support for one of its ends in the independent claim 13 or in the claim 5 itself. It is further unclear because of the lack of definiteness as to whether Applicant is claiming the combination or the subcombination. See paragraph above. (i.e. the injection device).

Claims 6 and 7 are indefinite because it is unclear which "end" of the injection device Applicant is referring to. Further, there is a lack of antecedent basis.

Claim 8 is vague and indefinite because it is unclear what "at their ends" is intended. It is further unclear what "ends" Applicant is referring to since it could be the end of the cartridge or the ends of the lateral walls.

Claim 9 recites the limitation "the studs" in line 3. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Art Unit: 3763

11. Claims 13, 4-7 are rejected under 35 U.S.C. 102(b) as being anticipated by Becton Dickinson and Company (BD and Co.) (GB 677,523) .

See figures 6-7 and 13. BD and Co. discloses cartridge having a receptacle (31) of preselected material and containing a single use quantity of pharmaceutical product, a single orifice (46) formed in the receptacle, the receptacle surrounded by an envelope (20) made of preselected material and covering the receptacle, an end cap (37) removably covering the end of the cartridge.

BD and Co. further discloses the an orifice at each end of the cylindrical cartridge and one end having a diameter substantially equivalent to the diameter of the rod (22) of the percussion member while the other orifice serves as a nozzle.

The means permitting engagement is interpreted as the tight fitting of the receptacle in the envelope.

As to the end cap, see fig. 12.

Claim Rejections - 35 USC § 103

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Art Unit: 3763

13. Claims 2-3 are rejected under 35 U.S.C. 103(a) as being unpatentable over Becton Dickinson and Company (BD and Co.) (GB 677,523) in view of Haber et al. (U.S. Patent No. 5,514,107) or Higgins et al. (U.S. Patent No.3,130,724) or Dufresne et al. (U.S. Patent No.4,830,217) or Bartner et al. (U.S. Patent No.3,894,633)

See figures 6-7 and 13. BD and Co. discloses the invention substantially as claimed. BD and Co. discloses the materials of the receptacle to be any suitable material (2:17-18) and shows the envelope (20) and the receptacle with different hatch marks to represent different materials. However, BD and Co. is silent to the specific materials used. Haber et al. or Higgins et al. or Dufresne et al. or Bartner et al. teach a glass receptacle having a plastic envelope in the same field of endeavor. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the materials used by BD and Co. as taught by Haber et al. or Higgins et al. or Dufresne et al. or Bartner et al. in order to provide a plastic envelope surrounding the glass would prevent the easy breakage of the glass receptacle. Further it would have been an obvious design choice as to the materials used to construct the first and second elements since it is well known to use glass and plastic materials in medical devices such as needleless injection devices.

14. Claims 13, 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Becton Dickinson and Company (BD and Co.) (GB 677,523) in view of Stiehl et al. (U.S. Patent No. 5,350,367).

BD and Co. teaches all the limitations of the claims except a plurality of plastic material gaps in the plastic overmould of the cartridge to produce slots for improving visibility of the first element.

Art Unit: 3763

Stiehl et al. teaches analogous art of a dispensing hypodermic syringe. Stiehl et al. teaches a first element of which is the glass receptacle which is inserted into a plastic holder through the open side wall. Stiehl et al. further discloses a viewing window (26) and it would be also inherent that through the open side wall the user can also view the contents of the glass receptacle. It would have been obvious to one of ordinary skill in the art at the time the invention was made to put a plurality of windows in the plastic second element of BD and Co. as taught by Stiehl in order to provide visibility of the medicament contained in the glass receptacle.

Allowable Subject Matter

15. Claim 8 is allowable as explained in the first office action.
16. Claim 9 is allowable since the prior art of record fails to teach a cap which encloses the distal end of the cartridge having lateral walls with raised zones which clip into impressions provided on the outer lateral walls of the cartridge.
17. Claim 10 is allowable since the prior art fails to teach or render obvious a cartridge having a receptacle, a single orifice formed in the receptacle, an envelope molded over the receptacle, an end cap covering the end of the cartridge that includes the single orifice in combination with the elements and further including an elastomeric seal located in the central portion of the end cap and further having the seal in the cap. It is the end product which is allowable and not the product by process of molding operation.

Art Unit: 3763

18. Claim 11 is allowable since the prior art of record fails to teach or render obvious a cartridge in combination with all the elements and further including an elastomeric seal attached and fitted into a recess provided by an internal surface of the end cap.

Response to Arguments

19. Applicant's arguments with respect to claims 1-7 have been considered but are moot in view of the new ground(s) of rejection.

Applicant's arguments with respect to page 11 of the remarks to the amendment is not considered persuasive since it is the intended use of the the doctor or nurse that the receptacle contains a single use of quantity of the drug.

Conclusion

20. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Grabenkort et al. (U.S. Patent No. 4,332,399) and Fournier et al. (U.S. Patent No. 4,982,769) discloses a cartridge made of glass and an envelope made of plastic.

21. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

Art Unit: 3763

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

22. Any inquiry concerning this communication or earlier communications from the examiner should be directed to LoAn H. Thanh whose telephone number is (703) 305-0038. The examiner can normally be reached on Monday-Thursday from 7:00 AM to 4:30 PM. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Wynn Wood Coggins, can be reached on (703) 308-1344. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-3590.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

LoAn H. Thanh

Patent Examiner

Art Unit: 3763

Date: August 4, 1999


WYNN WOOD COGGINS
SUPERVISORY PATENT EXAMINER